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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	9

DATE MAILED: 12/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/810,419	BARONE ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This action is in response to papers filed 8 October 2002 in Paper No. 8 in which page 18, lines 1-4 and 21-24 and claims 1-5 and 12-17 were amended. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 7 dated 3 July 2002 under 35 U.S.C. 112, second paragraph; under 35 U.S.C. 102(a); and under 35 U.S.C. 103 (a) are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-20 are under prosecution.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The Provisional Application filed 17 March 2000 upon which priority is claimed provides adequate support under 35 U.S.C. 112 for claims 1-20 of this application.

Applicant's comment regarding the filing date of the Provisional Application is acknowledged. The corrected date is noted above.

Specification

3. Applicant's amendment to the specification is acknowledged. The previous objection to the specification is withdrawn in view of the amendment.

Claim Objections

4. Applicant's amendment to Claim 2 is acknowledged. The previous objection to Claim 2 is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 13 are each indefinite for the recitation "wherein each different nucleic acid" because the recitation lacks proper antecedent basis in Claim 3 which recites "nucleic acids having different sequences". It is suggested that Claims 12 and 13 be amended to provide proper antecedent basis e.g. replace "different nucleic acid" with "nucleic acid having a different sequence".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-20 are rejected under 35 U.S.C. 102 (e) as anticipated by McGall et al (U.S. Patent No. 6,156,501, filed 3 April 1996).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 1, McGall et al disclose a method of preparing a nucleic acid array on a support wherein each nucleic acid occupies a separate known region of the support said method comprising: contacting said support with protected nucleoside phosphoramidite monomers (Column 6, line 45-Column 7, line 8) wherein the protected nucleoside phosphoramidite monomers have less than about 1 mole % of a phosphoramidite contaminant as measured by ^{1}H NMR spectrometry i.e. 98% pure (Examples 9 & 10, Column 22, line 35-Column 23, line 30).

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter in which there is reason to believe inherently includes functions that are newly cited or is identical to a product

instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

The claim is drawn to a phosphoramidite monomer having less than about 1% phosphoramidite contaminant. The "less than about 1%" encompasses a range of percentages including than 1% and less than 1%. The specification teaches a working example wherein the contaminant is presence at "~ 3-5 mole%" (Example 1,page 22, lines 1-4). However, the specification does not teach, define or limit the range of contaminants encompassed by the claim.

The 98% pure phosphoramidites of McGall are purified from a mixture including numerous components (see Column 22, lines 56-67 and Column 23, lines 21-29). Their 98% pure phosphoramidites would have, at most, 2% total contaminants, some of which would include the components listed in Examples 9 & 10 and some of which may include phosphoramidite contaminants. As such, the phosphoramidite contaminant would be much less than the total contaminants and therefore, much less than 2% contaminants. The instant claim is drawn to "about 1%" phosphoramidite contaminant which encompasses an undefined range of contaminants. McGall et al purifies phosphoramidites to 98% purity from a mixture comprising numerous components only some of which are phosphoramidite contaminants. Because the claim is drawn to an undefined amount of phosphoramidite and because McGall provides 98% pure phosphoramidites, the claimed instantly claimed phosphoramidites and the phosphoramidites of McGall are considered substantially identical. Therefore, the teaching of McGall anticipates the claimed method.

The burden is on applicant to show that the claimed monomers having less than about 1 mole % phosphoramidite contaminant are different from those of McGall et al.

Regarding Claim 2, McGall et al disclose the method further comprising: activating a region of the support; attaching a nucleotide to a first region said nucleotide having a masked

reactive site linked to a protecting group; repeating the activating and attaching on other regions of the support whereby each of said other regions has bound thereto another nucleotide comprising a masked reactive site linked to a protective group; removing the protective group from one of the nucleotides bound to one of the regions of the support to provide a region bearing a nucleotide having an unmasked reactive site; binding an additional nucleotide to the nucleotide to the nucleotide with an unmasked reactive site; and repeating the removing and binding until a desired plurality of nucleic acid is synthesized, each occupying separate known regions of the support (Column 6, line 45-Column 7, line 8) wherein the phosphoramidite contaminant is less than about 0.5 mole % as measured by ^{1}H NMR i.e. 98% pure (Column 14, lines 1-23).

The claim is drawn to a phosphoramidite monomer having less than about 0.5% phosphoramidite contaminant which encompasses more than and less than 0.5% contaminant. The specification does not teach, define or limit the range contaminants encompassed by the claimed "less than about 0.5%".

The 98% pure phosphoramidites of McGall are purified from a mixture including numerous components (see Column 22, lines 56-67 and Column 23, lines 21-29). The 98% pure phosphoramidites would have, at most, 2% contaminants, some of which would include the components listed in Examples 9 & 10 and some of which may include phosphoramidite contaminants. Because the claim is drawn to "about 0.5%" phosphoramidite contaminants which encompasses an undefined range of contaminants and because McGall et al purifies phosphoramidites to 98% purity from a mixture comprising numerous components only some of which are phosphoramidite contaminants, the claimed phosphoramidite and the phosphoramidites of McGall are considered substantially identical. Therefore, the teaching of McGall anticipates the claimed phosphoramidites.

The burden is on applicant to show that the claimed monomers having less than about 0.5 mole % phosphoramidite contaminant are different from those of McGall et al.

Regarding Claim 3, McGall et al disclose the method further comprising: generating a pattern of light and dark areas by selectively irradiating at least a first area of a surface said surface comprising immobilized nucleotides said nucleotides capped with a photoremovable groups without irradiating at least a second area of said surface to remove said protective group simultaneously contacting said first area and said second area with a first nucleotide to couple said first nucleotide to said immobilized nucleotides and not it said second area said first nucleotide capped with said photoremovable protective group; generating another pattern of light and dark areas by selectively irradiating with light at least a part of said first area and at least a part of a second area to remove said protective group; simultaneously contacting said first area and said second areas with a second nucleotide to couple said second nucleotide to said immobilized nucleotides; performing additional irradiating and nucleotide contacting and coupling steps (Column 6, line 45-column 7, line 8 and Fig. 2) so that a matrix array of at least 100 nucleic acids having different sequences is formed on said support (Column 6, lines 50-53).

Regarding Claim 4, McGall et al disclose the method of Claim 1 wherein the phosphoramidite is 98% pure as measured by 1H NMR spectrometry (Examples 9 and 10, Column 22, line 35-Column 23, line 30).

The claim is drawn to a phosphoramidite monomer having less than about 0.2% phosphoramidite contaminant which encompasses more than and less than 0.2% contaminant. The specification does not teach, define or limit the range contaminants encompassed by the claimed "less than about 0.2%".

The 98% pure phosphoramidites of McGall are purified from a mixture including numerous components (see Column 22, lines 56-67 and Column 23, lines 21-29). The 98% pure phosphoramidites would have, at most, 2% contaminants, some of which would include the components listed in Examples 9 & 10 and some of which may include phosphoramidite contaminants. Because the claim is drawn to "about 0.2%" phosphoramidite contaminants

which encompasses an undefined range of contaminants and because McGall et al purifies phosphoramidites to 98% purity from a mixture comprising numerous components only some of which are phosphoramidite contaminants, the claimed phosphoramidite and the phosphoramidites of McGall are considered substantially identical. Therefore, the teaching of McGall anticipates the claimed phosphoramidites.

The burden is on applicant to show that the claimed monomers having less than about 0.2 mole % phosphoramidite contaminant are different from those of McGall et al.

Regarding Claim 5, McGall et al disclose the method having the claimed formula wherein B is a member selected from the group consisting of adenine, guanine, thymine, cytosine, uracil and analogs thereof; R is a member selected from the group consisting of hydrogen, hydroxyl, protected hydroxy, halogen, and alkoxy; P is a phosphoramidite group; and PG is a photoremovable group (Column 23, line 65-Column 24).

Regarding Claim 6, McGall et al disclose the method wherein B is selected from the group consisting of adenine, guanine, thymine, cytosine and R is a hydrogen (Column 23, line 65-Column 24).

Regarding Claim 7, McGall et al disclose the method of Claim 5 wherein said array comprises at least 10 different nucleic acids (Column 6, lines 50-53 and Column 1, lines 59-67).

Regarding Claim 8, McGall et al disclose the method of Claim 5 wherein said array comprises at least 100 different nucleic acids (Column 1, lines 59-67).

Regarding Claim 9, McGall et al disclose the method of Claim 5 wherein said array comprises at least 1,000 different nucleic acids (Column 1, lines 59-67).

Regarding Claim 10, McGall et al disclose the method of Claim 5 wherein said array comprises at least 10,000 different nucleic acids (Column 1, lines 59-67).

Regarding Claim 11, McGall et al disclose the method of Claim 5 wherein said array comprises at least 100,000 different nucleic acids (Column 1, lines 59-67).

Regarding Claim 12, McGall et al disclose the method of Claim 5 wherein each different nucleic acid is in a region having an area of less than about 1 cm^2 (Column 1, line 67-Column 2, line 4).

Regarding Claim 13, McGall et al disclose the method of Claim 5 wherein each different nucleic acid is in a region having an area of less than about 1 mm^2 (Column 1, line 67-Column 2, line 4).

Regarding Claim 14, McGall et al disclose the method of Claim 5 wherein the phosphoramidite is 98% pure as measured by 1H NMR spectrometry (Examples 9 and 10, Column 22, line 35-Column 23, line 30)

Regarding Claim 15, McGall et al disclose the method of Claim 5 wherein B is selected from the group consisting of adenine, guanine, thymine, cytosine and R is a hydrogen (Column 2, lines 13-44 as recited in Claim 15) and wherein the phosphoramidite is 98% pure as measured by 1H NMR spectrometry (Examples 9 and 10, Column 22, line 35-Column 23, line 30).

Regarding Claim 16, McGall et al disclose the method of Claim 5 wherein B is selected from the group consisting of adenine, guanine, thymine, cytosine; R is a hydrogen (Column 2, lines 13-44 as recited in Claim 15); PG is MeNPOC (Column , lines 51-65) and wherein the phosphoramidite is 98% pure as measured by 1H NMR spectrometry (Examples 9 and 10, Column 22, line 35-Column 23, line 30).

Regarding Claim 17, McGall et al disclose the method of Claim 5 wherein B is selected from the group consisting of adenine, guanine, thymine, cytosine; R is a hydrogen (Column 2, lines 13-44 as recited in Claim 15); PG is MeNPOC; and P is P-(OCH_2HC_2CN)N(iPr)2 (Examples 9 & 10, Column 22, line 35-Column 23, line 30) and wherein the phosphoramidite is 98% pure as measured by 1H NMR spectrometry (Examples 9 and 10, Column 22, line 35-Column 23, line 30).

Claims 14-15 are drawn to a phosphoramidite monomer having less than about 0.2% phosphoramidite contaminant which encompasses more than and less than 0.2% contaminant. The specification does not teach, define or limit the range of contaminants encompassed by the claimed "less than about 0.2%".

The 98% pure phosphoramidites of McGall are purified from a mixture including numerous components (see Column 22, lines 56-67 and Column 23, lines 21-29). The 98% pure phosphoramidites would have, at most, 2% contaminants, some of which would include the components listed in Examples 9 & 10 and some of which may include phosphoramidite contaminants. Because the claim is drawn to "about 0.2%" phosphoramidite contaminants which encompasses an undefined range of contaminants and because McGall et al purifies phosphoramidites to 98% purity from a mixture comprising numerous components only some of which are phosphoramidite contaminants, the claimed phosphoramidite and the phosphoramidites of McGall are considered substantially identical. Therefore, the teaching of McGall anticipates the claimed phosphoramidites.

The burden is on applicant to show that the claimed monomers having less than about 0.2 mole % phosphoramidite contaminant are different from those of McGall et al.

Regarding Claims 18-20, McGall et al disclose nucleic acid arrays prepared by the methods of Claims 1, 5 and 17 (Example 12, Column 23, line 65-Colimmn 24, line 65).

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
December 23, 2002